

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. 7,411,050
Issue date August 12, 2008
Inventors Dirk M. Anderson
For MONOCLONAL BLOCKING ANTIBODY TO HUMAN RANKL

Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

SUPPLEMENT TO APPLICATION FOR EXTENSION OF PATENT TERM
UNDER 35 U.S.C. § 156

Further to the Application for Extension of Patent Term Under 35 U.S.C. § 156 dated July 27, 2010 ("the Application"), Applicant submits the following information.

In addition to regulatory review under Section 505 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355, of the investigational new drug application (IND), the approved product was also subject to regulatory review under Section 351 of the Public Health Service Act, 42 U.S.C. § 262, of the biologic license application (BLA). That information is evident from, for example, the Application's disclosure at pages 4-7, disclosing information concerning the IND and BLA.

Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought in this application.

The prescribed fee for receiving and acting upon the application for extension of \$1,120.00 was enclosed with the Application. Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 06-0916 for any such fees. Should a refund of fee paid be necessary, the Commissioner is hereby authorized to credit any such amount to Deposit Account No. 06-0916.

The undersigned is a registered practitioner of the United States Patent and Trademark Office and is authorized by the Applicant to act on behalf of the Applicant.

Respectfully submitted,

Date: 09 September 2010

Charles E. Van Horn
Charles E. Van Horn
Reg. No. 40,266

CERTIFICATION

The undersigned hereby certifies that this supplement to the application for extension of patent term under 35 U.S.C. § 156 is being submitted with two additional copies of originals.

Date 09 September 2010

Charles E. Van Horn
Charles E. Van Horn
Reg. No. 40,266